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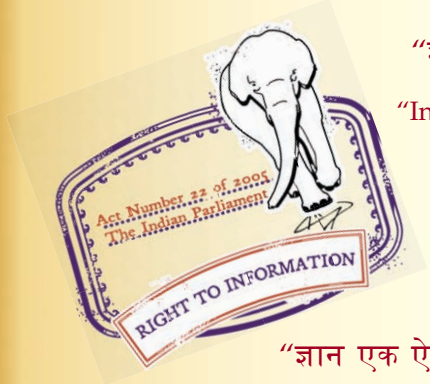
IS 11754 (1986): Implantable Ventricular Pacemaker [MHD 19: Immuno-Biological Diagnostic Kits]



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"Knowledge is such a treasure which cannot be stolen"

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IS : 11754 - 1986
(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR IMPLANTABLE VENTRICULAR PACEMAKER

UDC 615·841 : 615·817

INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr 6

February 1987

Indian Standard

SPECIFICATION FOR IMPLANTABLE VENTRICULAR PACEMAKER

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Indian Standard

SPECIFICATION FOR IMPLANTABLE VENTRICULAR PACEMAKER

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 24 July 1986, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Electrotechnical Division Council.

0.2 This standard covers the requirements of implantable ventricular pacemakers. Although an electromedical device, an implantable pacemaker should nevertheless be considered separately from standards which cover electromedical equipment in general. Where the focus of general electromedical equipment is on safety in the patient environment, which is usually considered external to the patient, the implantable pacemaker has different safety aspects.

0.3 There are many kinds of cardiac pacemakers which differ in ways in which they maintain and control cardiac activity under diverse circumstances. The simplest kind of pacemaker stimulates the ventricle independently of cardiac activity; some pacemakers monitor ventricular activity and stimulate the ventricles as and when required. Other more sophisticated pacemakers depend on monitoring and/or stimulating the ventricle and/or the atrium. Some implantable pacemakers operate at preset values of rate, amplitude and duration. Others may have one or more parameter values controlled non-invasively by means of an external programmer. Those pacemakers which require long-term attachment of an external controller over the implanted pacemaker are deemed to be only partially implantable. Those which require the presence of the controller only to activate the pacemaker programming feature are deemed wholly implantable. Thus the possible ways in which cardiac pacing can be achieved are numerous and complex.

0.4 While preparing this standard, assistance has been derived from ISO/DIS 5841/1 'Implants for surgery — Cardiac pacemakers : Part 1 Implantable ventricular pacemakers', issued by the International Organization for Standardization (ISO).

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard specifies the requirements of wholly implantable ventricular pacemakers.

1.2 The standard applies exclusively to wholly implantable cardiac pacemakers, either of preset or the programmable type, and is conforming to those aspects of pacemakers which are concerned only with stimulation of the ventricle (asynchronous pacing) and with sensing and stimulation of the ventricle (ventricular inhibited or ventricular triggered pacing).

2. TERMINOLOGY

2.0 The following definitions in addition to those given in IS : 1885 (Part 42)-1977† and IS : 8607 (Part 1)-1977‡ shall apply.

2.1 Adaptor — Specialized connector used between pulse generator and lead which are otherwise incompatible.

2.2 Electrode — Electrically conductive element (usually a termination of a lead) which interfaces with body tissue.

2.3 Hysteresis — The characteristic of a pulse generator in which the escape pulse interval (rate) is longer (slower) than the basic pulse interval (rate).

2.4 Lead — Means of electrically connecting a pulse generator to the heart.

2.5 Lead Bipolar — Lead with two electrically isolated electrodes.

2.6 Lead Endocardial — Lead with an electrode designed to contact the endocardium or inner surface of the heart.

2.7 Lead Epicardial — Lead with an electrode designed to contact the epicardium or outer surface of the heart.

2.8 Lead, Myocardial — Lead with an electrode(s) designed to be inserted into the myocardium.

*Rules for rounding off numerical values (*revised*).

†Electrotechnical vocabulary: Part 42 Power capacitors.

‡General and safety requirements for electrical equipment used in medical practice: Part 1 General.

2.9 Lead Unipolar — Lead with one electrode.

2.10 Leading Edge — Initial portion of the pulse from zero to its peak amplitude.

2.11 Marking — Any display of written, printed or graphic matter appearing on or affixed to a device or appearing on a package containing a device.

2.12 Model Designation — Name or group of letters and/or numbers designated by a manufacturer distinguishing one device from another by function or type.

2.13 Nominal Service Life of Pulse Generator — An estimate of the expected implant life time of a given model of pulse generator, taking into account the usable battery capacity, which enables the pulse generator performances characteristics to remain within defined limits under specified conditions, and ignoring the possibility of any cause of failure other than that due to battery discharge.

2.14 Pacemaker (Pacer) — Device for stimulating the heart comprising a pulse generator and a lead(s).

2.15 Package — Any container or wrapping material in which a device is wholly or partly contained, placed or packed.

2.16 Package, Shipping — Package in which the pulse generator, lead, accessory or combination thereof is supplied and which is not intended to be a storage package.

2.17 Package, Sterilized — Package in which a pulse generator, lead, accessory or combination thereof has been through a sterilization process.

2.18 Package, Storage — Package in which by a pulse generator, lead adaptor or combination thereof is intended by the manufacturer to be stored at the implanting centre.

2.19 Pervenous — Indirect approach to the heart through the venous system.

2.20 Pulse Amplitude, Measured — Amplitude value measured by the manufacturer prior to shipment.

2.21 Pulse Duration, Measured — Pulse duration measured by the manufacturer prior to shipment.

2.22 Pulse Rate(s), Measured — Pulse rate(s) measured by the manufacturer prior to shipment.

2.23 Pulse Generator — Portion of the pacemaker that produces a periodic electrical pulse and includes the power supply and electronic circuit.

2.24 Pulse Generator, Asynchronous — Pulse generator in which the pulse rate is independent of the activity of the heart.

2.25 Pulse Generator, Ventricular Inhibited — Ventricular stimulating pulse generator which is intended to suppress its output in response to natural ventricular activity and produces an output at its basic pulse rate in the absence of natural ventricular activity.

2.26 Pulse Generator, Ventricular Triggered — Ventricular stimulating pulse generator which is intended to deliver its output synchronously with the natural ventricular activity and at its basic pulse rate in the absence of natural ventricular activity.

2.27 Pulse Interval — Time interval between selected identical points on the pulses of two consecutive output pulses of pulse generator expressed in milliseconds.

2.28 Pulse Interval, Basic (Basic Pulse Period) — The pulse interval free from modifying cardiac or other electromagnetic influence.

2.29 Pulse Interval, Escape — Time between the sensing of a spontaneous beat and the succeeding non-triggered output pulse of a pulse generator free from modifying cardiac activity or other electromagnetic influences.

2.30 Pulse Rate — The number of pulses per minute (abbreviated as ppm).

2.31 Pulse Rate, Basic — Pulse rate free from modifying cardiac activity or other electromagnetic influence.

2.32 Pulse Rate, Interference — Pulse rate of a pulse generator when an electromagnetic field is recognized as interference.

2.33 Pulse Rate, Test — Pulse rate of a pulse generator when under the influence of a testing device.

2.34 Refractory Period — Period during which a pulse generator is unresponsive to an input signal of specified amplitude.

2.35 Sensitivity (Sensing Threshold) — Measure in millivolts of the minimum signal required to control consistently the pulse generator function.

2.36 Sensitivity, Measured — Sensitivity measured by the manufacturer prior to shipment.

2.37 Serial Number — Unique combination of letters or numbers, or both, selected by the manufacturer to identify any part of a pacemaker.

2.38 Use-Before Date — Date specified by the manufacturer after which the pulse generator should not be implanted.

3. CODE FOR TYPE OF PULSE GENERATOR

3.1 The code to be used for marking the pulse generator to designate its primary intended use is described in **3.2** to **3.5**. Multiple programmable or universal pacemakers are not covered in the code.

3.2 Outline of the basic concept of the code is as follows:

a) *First Letter* — Chamber paced

b) *Second Letter* — Chamber sensed

c) *Third Letter* — Mode of response

3.3 In the code, the following abbreviations shall be used:

V = ventricle	*I* = Inhibited
A = Atrium	*T* = Triggered
D = Double chamber	*O* = Not applicable

3.4 The code letter significance is explained below:

a) *First Letter* — The paced chamber is identified by *V* for ventricle, *A* for atrium, or *D* for double (that is, both atrium and ventricle).

b) *Second Letter* — The sensed chamber is identified by either *V* for ventricle, or *A* for atrium. An *O* indicates that the pulse generator has no sensing function.

c) *Third Letter* — The mode of response is either:

1) *I* for inhibited (that is, a pulse generator whose output is blocked by a sensed signal), or

2) *T* for triggered (that is, a pulse generator whose output is triggered by a sensed signal), or

3) *O* for pulse generator having no sensing function.

3.5 Some examples of code application are given below:

Type of Pulse Generator	*Explanation of Code Used*
VOO :	Ventricular pacing, no sensing function
AOO :	Atrial pacing, no sensing function
DOO :	Double-chamber pacing, no sensing function
VVI :	Ventricular pacing and sensing, inhibited mode

Type of Pulse Generator	*Explanation of Code Used*
VVT :	Ventricular pacing and sensing, triggered mode
AAI :	Atrial pacing and sensing, inhibited mode
AAT :	Atrial pacing and sensing, triggered mode
VAT :	Ventricular pacing, atrial sensing, triggered mode
DVI :	Double-chamber pacing, ventricular sensing, inhibited mode

4. PACKING, MARKING AND ACCOMPANYING DOCUMENTS

4.1 Packing and Marking

4.1.1 *Packing* — Packages shall be classified as:

a) Shipping packages,

b) Storage packages, and

c) Sterilizer packages.

4.1.2 *General Package Markings* — Each package shall have legible and indelible markings which shall be of material that will maintain legibility during normal handling and not adversely affect the contents. The storage and sterilizer package shall have instructions for proper unpacking of the contents so as to prevent physical damage and maintain sterility.

4.2 Shipping Package

4.2.1 *Marking* — The following information shall be included in shipping package markings:

a) Identification of the contents,

b) Manufacturer (and agent/distributor, if different from manufacturer) information, with complete address, and

c) Warnings concerning handling and storage during shipment.

4.2.2 *Contents* — The shipping package shall contain the storage packages.

4.3 Storage Package

4.3.1 *Marking* — The following information specific to the contents shall be included:

a) Manufacturer's name or trade-mark and location;

b) Space for the agent's name, address and telephone number; and

c) Contents of the sterilized packages, namely, pulse generator (type, model designation, serial number) or lead (type, model designation, serial number) or pulse generator and packing lead, together with a list of accessories, if any; and

d) Pulse generator parameters at 37 + 2°C with 510 Ω ± 2 percent load:

1) Measured basic pulse rate;

2) Measured test pulse rate, if applicable (ppm);

3) Measured amplitude (V or mA);

4) Measured pulse duration (ms); and

5) Measured sensitivity, if applicable (mV).

NOTE — In the case of adjustable pulse generators, the parameters shall refer to the generators as shipped. The values of all other parameters upon which all of the above are dependent shall be given.

e) Statement as to which of the characteristics are adjustable;

f) Statement to the effect that contents of the packages have been through a sterilization process;

g) Use-before date,

h) Recommendations regarding storage and handling; and

j) Warnings which shall be prominently displayed.

4.3.2 *Contents* — The storage package shall contain accompanying documentation and sterilized packages.

4.4 Accompanying Documentation

4.4.1 *Manual for Medical Personnel* — The manual shall give information as indicated in **4.4.1.1** to **4.4.1.5** about the pulse generator and/or lead, as the case may be.

4.4.1.1 *Supplier's details* — The name, address, and telephone numbers of the manufacturer (or responsible agent) shall be provided.

4.4.1.2 *Handling instructions* — Instructions shall be provided for opening the sterilized package. Recommendations shall be provided regarding handling and storage conditions.

4.4.1.3 *Pulse generator* — The following details shall be provided:

a) Type and model designation (and name, if applicable).

b) General description and explanation and function.

c) Type of power source.

d) Physical characteristics, such as:

1) Mass (g),

2) Principal dimensions (mm), and

3) Volume (cm^3).

e) Material, surface area (cm^2) and form of the electrode which is an integral part of the pulse generator (if applicable).

f) Electrical characteristics at 37 ± 2°C and 510 Ω ± 2 percent load unless otherwise stated (including tolerance, where applicable) as follows:

1) Range of basic, test, escape and interference pulse rates and equivalent pulse intervals (if applicable);

2) Acceptable change in basic pulse rate during an initial stated time period;

3) Pulse shape, a diagram of a typical output pulse;

4) Pulse amplitude;

5) Pulse duration (range and stability);

6) Input impedance, if applicable;

7) Sensitivity range for both positive and negative polarity, if applicable; a description of the waveform used shall be included;

8) Refractory period (pacing and sensing), if applicable;

9) Operational characteristics when subjected to environmental electric, electromagnetic and magnetic fields; and

10) Programmable parameters shall have their values/ranges stated with recommended programmes.

g) Projected curves shall be provided which correlate battery depletion that is, the state of battery discharge, with the pulse generator characteristics which are listed below. These curves should be representative of the pulse generators and should be given for the temperature 37 ± 2°C and 510 Ω ± 2 percent load:

1) Basic pulse rate,

2) Test pulse rate (if applicable),

3) Pulse duration,

4) Pulse amplitude, and

5) Sensitivity (if applicable).

NOTE — It shall state which of the parametric changes can be used as power source depletion indicators and shall state the maximum changes which should be allowed to take place before consideration be given to explanting generators.

h) Curves shall be provided which show the typical variation of the following pacemaker parameters with temperature over the range 20 to 43°C:

1) Basic pulse rate,

2) Pulse duration,

3) Pulse amplitude,

4) Sensitivity (if applicable), and

5) Input impedance (if applicable).

j) Information on non-invasive identification.

k) Recommendations regarding choice of suitable lead and information on some compatible adaptors.

m) Specific implantation considerations regarding attachment of leads.

n) Recommended methods for determining that the implanted pacemaker is functioning properly.

p) Warnings regarding therapeutic energy sources, for example, external cardioversion, diathermy, cautery or other.

q) Information regarding registration.

r) Recommendations regarding resterilization including warnings pertaining to adverse methods of resterilization.

s) Recommendations for disposal of pulse generators.

t) Nominal pulse generator service life according to 7, and

u) Address from which longevity experience data can be obtained, if applicable.

4.4.1.4 *Lead* — The following details shall be provided:

a) Type, model designation and name, if applicable;

b) General description including conductor, conductor insulation materials and shape of electrodes;

c) Physical dimensions (including applicable tolerances):

1) Length (cm);

2) Surface area of electrodes (mm^2);

3) Maximum diameter of pervenous lead (except for connector end) (mm):

4) Distance between electrodes (bipolar endocardial lead) (mm);

5) Maximum depth of penetration, if applicable (mm);

6) Connector size (mm); and

7) Resistance of each conductor.

d) Recommendations regarding use with pulse generators;

e) Recommendations regarding resterilization including warnings;

f) Specific implantation considerations regarding attachment of leads; and

g) Precautions during handling to avoid damage to the lead.

4.4.1.5 *Adaptor (if applicable)* — The following details shall be provided:

a) Type, model designation (and name, if applicable);

b) General description including conductor and conductor materials; and

c) Compatibity with pulse generators and leads.

4.4.2 *Registration Form* — A registration form for recording basic patient and implantation information shall be provided. The registration form should be in duplicate with one part marked 'For return to the manufacturer'.

Space shall be provided on the form for the following information:

a) Patient data (required for patient identification card);

b) Type of pulse generator, model designation and serial number;

c) Date on which pulse generator was implanted;

d) Type of pacing lead(s), model designation(s) and serial number(s) and implantation date;

e) Telephone number(s) of medical personnel hospital to contact; and

f) Medical personnel hospital address.

4.4.3 *Patient's Identification Card* — The manufacturer shall supply to the implanting centre, an identification card. Space shall be provided on the card for at least the following information, where applicable:

a) Patient's name, address, telephone number and identification code suitable for computer data processing;

b) Name, address and telephone number of hospital where pacemaker was implanted;

c) Name, address and telephone number of clinician responsible for patient's care;

d) Name, address and telephone number of pacemaker manufacturer/ agent;

e) Dates of implantation of pulse generator and leads;

f) Type of pulse generator, model designation and serial number;

g) Measured generator ratings (basic pulse rate, test and escape pulse rates), if applicable; and

h) Type of lead(s), model designation(s) and serial number(s).

4.4.4 *Explantation Form* — An explantation form shall be provided. The form should be in duplicate, with one part marked for return to the manufacturer. Separate forms may be provided for pulse generator and leads. The form should request for the following:

a) Patient data:
   1) Patient's name/identification code;
   2) Patient's address, and
   3) Name and address of medical personnel responsible for patient care.

b) Data on pulse generators and leads:
   1) Manufacturer, type, model designation, serial number and dates of implantation and explantation of removed pulse generators;
   2) Reason for replacement of pulse generators: apparent change in pulse generator characteristics prophylactic replacement (elective replacement), other reason;

3) Data on leads: manufacturer, type, model designation, serial number and date of implantation and explantation of removed lead;

4) Reason for replacement of lead: apparent change in lead structure, exit block, high threshold, displacement of lead, infection, extrusion, other reason; and

5) Evidence (electrocardiographic, electronic, etc) which shows the pacemaker performance prior to its removal (if applicable).

4.5 Sterilized Package

4.5.1 *Sterilized Package Marking* — The sterilized package marking shall include the following:

a) Contents of the sterilized package, namely, pulse generator (type, model designation, serial number) or lead (type, model, designation, serial number) or pulse generator and pacing lead, together with a list of accessories, if any;

b) Pulse generator parameters at $37 \pm 2°C$ and $510\ \Omega \pm 2$ percent load:

1) Measured basic pulse rate (ppm);

2) Measured test pulse rate, if applicable (ppm);

3) Measured pulse amplitude (V or mA);

4) Measured pulse duration (ms); and

5) Measured sensitivity (mV).

NOTE — In case of adjustable pulse generators, the parameters shall refer to the generator as shipped.

c) Statement as to which of the characteristics are adjustable;

d) Statement to the effect that the package and its contents have been subjected to a sterilization process;

e) Use before date;

f) Any warnings which shall be prominently displayed; and

g) Instructions for opening.

4.5.2 *Sterilized Package Contents* — The pulse generator, lead and necessary accessories/adaptors (either separately or in combination) shall be supplied in a sterilized package capable of maintaining the sterility of the

product during shipping and under conditions of normal storage and handling, and to allow the contents to be presented for use in an aseptic manner. The sterilized package should not be resealable.

4.6 Pulse Generators, Leads and Adaptors

4.6.1 *Pulse Generator Markings* — The marking on a pulse generator shall be permanent, readily readable and give the following information :

a) Name and location of manufacturer,

b) Type,

c) Model designation,

d) Serial number, and

e) An appropriate designation, if the pulse generator has characteristics which are not generally available from the manufacturer.

4.6.2 *Non-invasive Identification of Pulse Generators* — The method of identification shall be a code consisting of radiopaque letter, number and/or symbol incorporated into the pulse generator to allow the medical personnel to identify the pulse generator non-invasively, with appropriate code information.

The identifiable information shall indicate at least the manufacturer and the model of the particular pulse generator, allowing subsequent identification of the pulse generator performance characteristics.

4.6.3 *Markings on Leads and Adaptors* — Each lead or adaptor shall be permanently and visibly marked for identification of serial number and manufacturer. The manufacturer shall supply a code available to public by which the leads (and adaptors) shall be identified.

5. PULSE GENERATOR TESTS

5.1 General — The following test methods and procedures are provided as a basis for evaluation of basic parameters of pacemaker. The purpose is to allow gross assessment of pacemaker function without elaborate instrumentation and equipment.

5.1.1 The tests are to be performed with the pulse generator at 37 $\pm$ 2°C.

5.2 Test Equipment

5.2.1 *Test Load* — 510 Ω $\pm$ 2 percent resistance load (at 37°C).

5.2.2 *Oscilloscope (Dual Trace)*

a) Minimum sensitivity : V/cm (nominal)

b) Maximum rise time : 10 μs

c) Minimum input impedance : 1 M Ω

d) Maximum input capacitance : 50 pF

e) Calibration accuracy: $\pm$ 3 percent

5.2.3 *Interval (Period) Counter*

a) Minimum input impedance : 1 M Ω

b) Measurement accuracy : 0·1 percent

5.2.4 *Signal Generator for Sensitivity Measurements*

a) Maximum output impedance: 1 K Ω

b) Polarity test signal : to be available in both the polarities.

5.2.5 *Triggerable 2 Pulse Signal Generator for Measurement of Sensing and Pacing Refractory Period* — The waveform as specified by the manufacturer with the delay, independent for each pulse adjustable from 0 to 2 s, *Min* and a cycle period adjustable up to 4 s (during this period, the generator is not retriggerable).

5.3 Measurement of Pulse Amplitude, Pulse Duration and Pulse Interval (Pulse Rate)

5.3.1 *Circuit* — Test equipment and pulse generator shall be connected as shown in Fig. 1.

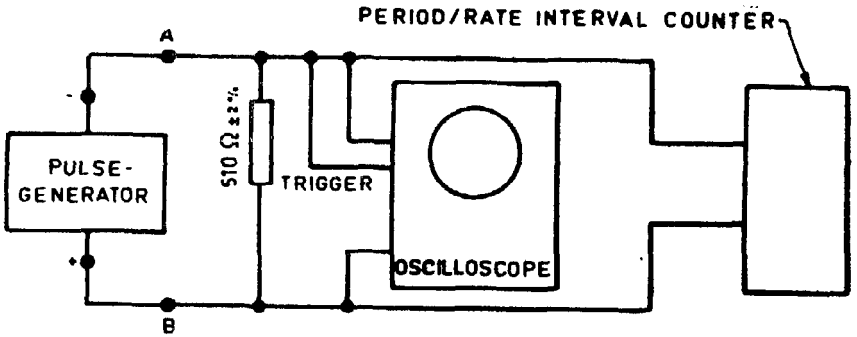


FIG. 1 CIRCUIT DIAGRAM FOR PULSE AMPLITUDE, PULSE DURATION AND PULSE INTERVAL MEASUREMENTS

5.3.2 *Method* — Adjust the oscilloscope to display one pulse from pulse generator leading for trailing edge. Measure pulse amplitude and duration at the points on the waveform specified by the manufacturer.

5.3.2.1 To measure pulse interval, set the interval counter to be triggered by the leading edge of the pulse generator pulse. The display on the interval counter gives the pulse interval. The pulse rate (if calculated) should be determined from pulse interval averaged over a minimum of 20 pulses.

5.4 Measurement of Sensitivity (Sensing Threshold)

5.4.1 *Circuit* — The test equipment and pulse generator shall be connected as shown in Fig. 2.

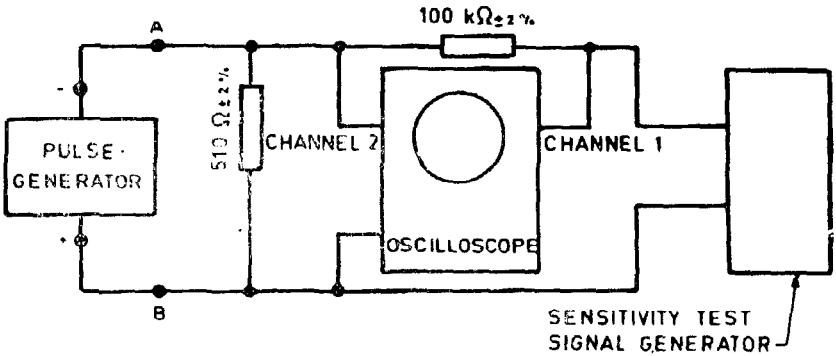


FIG. 2 CIRCUIT DIAGRAM FOR SENSITIVITY MEASUREMENTS

5.4.2 *Methods*

5.4.2.1 *Method using positive pulses*

5.4.2.1.1 Apply a positive signal from the sensitivity test signal generator to the point *A*. Adjust to a rate 10 pulse/min higher than the basic rate of the pulse generator.

5.4.2.1.2 Adjust the test signal amplitude to zero.

5.4.2.1.3 Adjust the oscilloscope to display several pulses from the pulse generator.

5.4.2.1.4 Increase the test signal amplitude slowly until:

a) the pulse generator pulse consistently vanishes (for ventricular inhibited pulse generators), or

b) the pulse generator pulses consistently occur simultaneously with the test signal (for ventricular triggered pulse generators).

5.4.2.1.5 The test signal generator voltage divided by 200 is the positive sensitivity amplitude, that is, *e* positive.

5.4.2.2 *Method using negative pulses*

5.4.2.2.1 Repeat the sequence in **5.4.2.1** with a negative test signal at *A*.

5.4.2.2.2 The test signal generator voltage divided by 200 is the negative sensitivity amplitude, or *e* negative.

5.5 Measurement of Input Impedance

5.5.1 *Circuit* — The test equipment and pulse generator shall be connected as shown in Fig. 3.

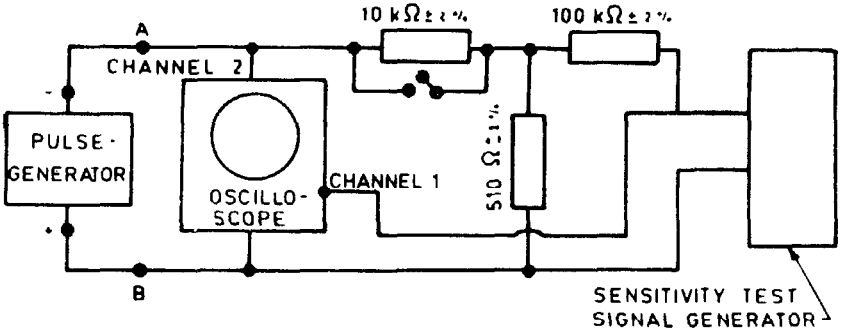


FIG. 3 CIRCUIT DIAGRAM FOR INPUT IMPEDANCE MEASUREMENTS

5.5.2 *Method*

5.5.2.1 Adjust the test signal amplitude from zero up to value e_1 positive when the pulse generator just consistently inhibits or triggers, as the case may be.

5.5.2.2 Open the switch and readjust the output from the test signal generator up to value e_2 positive when condition given in **5.5.2.1** is restored.

5.5.2.3 Calculate input impedance, Z_{in}, of the pulse generator under test from the formula, assuming $Z_{in} \geqslant 510\Omega$:

$$Z_{in} = \frac{100\, e_1}{e_2 - e_1}$$

5.6 Measurement of Escape Interval

5.6.1 *Circuit* — Connect the test equipment and pulse generator as shown in Fig. 4.

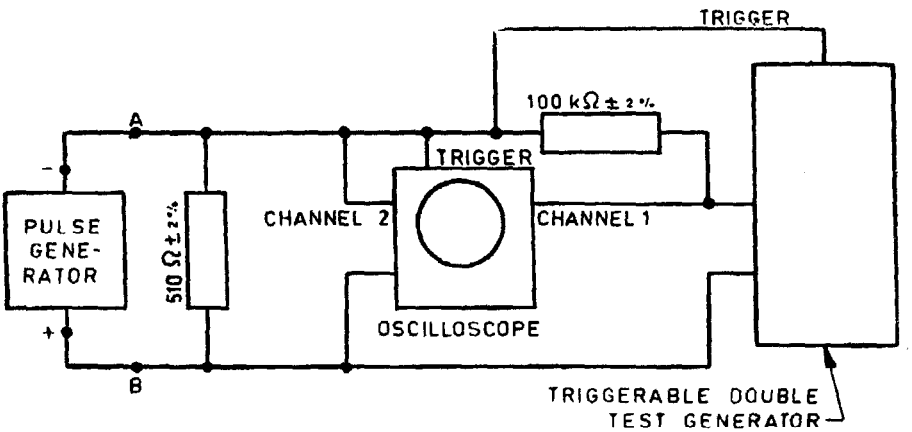


FIG. 4 CIRCUIT DIAGRAM FOR MEASUREMENT OF ESCAPE INTERVAL AND REFRACTORY INTERVALS

5.6.2 *Method*

5.6.2.1 Adjust the signal generator until the amplitude of the test signal is approximately $2e$ positive. Only single pulses are required from the triggerable double pulse signal generator with a delay (T) between triggering and production of pulse which is slightly greater than the interval (P) of the pulse generator on test.

5.6.2.2 Adjust the oscilloscope and signal generator so that the display as depicted in Fig. 5 is obtained (the test pulse and the pulse generator pulse both appear as lines).

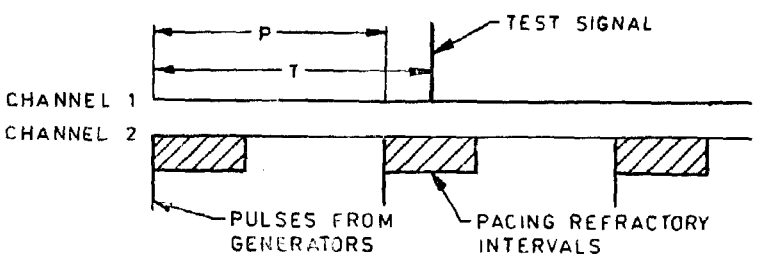
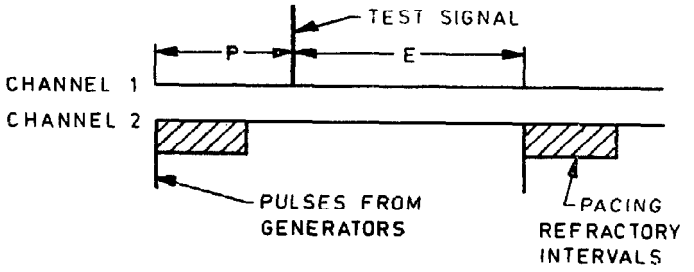


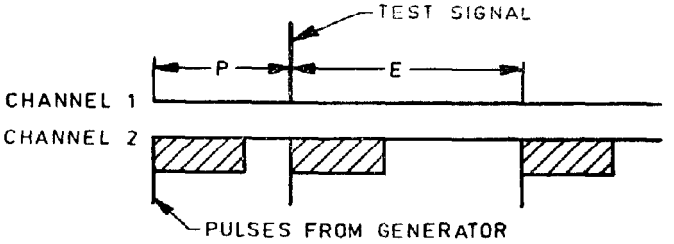
FIG. 5 INITIAL OSCILLOSCOPE DISPLAY WHEN MEASURING ESCAPE INTERVAL

5.6.2.3 Reduce the test signal delay until the test pulse is no longer in a pulse generator refractory interval. If an inhibited type pulse generator is being tested, then the display as shown in Fig. 6 will be obtained. If a triggered (synchronous) pulse generator is being tested, then the display shown in Fig. 7 will be obtained.



NOTE — P is the basic pulse interval in the absence of ventricular signals; $E = P$ for generators with hysteresis.

FIG. 6. MEASUREMENT OF ESCAPE INTERVAL (E) WITH VENTRICULAR INHIBITED PULSE GENERATOR



NOTE — P is the basic pulse interval in the absence of ventricular signals; $E = P$ for generators with hysteresis.

FIG. 7 MEASUREMENTS OF ESCAPE INTERVAL (E) WITH VENTRICULAR TRIGGERED (SYNCHRONIZED) PULSE GENERATOR

5.7 Measurement of Sensing Refractory Interval

5.7.1 *Circuit* — Connect the pulse generator output terminals to the test load, oscilloscope and triggerable double pulse signal generator (*see* **5.2.5**) as shown in Fig. 4.

5.7.2 *Method*

5.7.2.1 Adjust the signal generator so that pairs of pulses are produced by the triggerable double pulse signal generator. The pulses should be as close as possible to each other with delay (T) being slightly greater than the pulse interval of the pulse generator on test and they should have an amplitude of approximately 2e positive.

5.7.2.2 Adjust the oscilloscope and signal generator so that the display depicted in Fig. 8 is obtained.

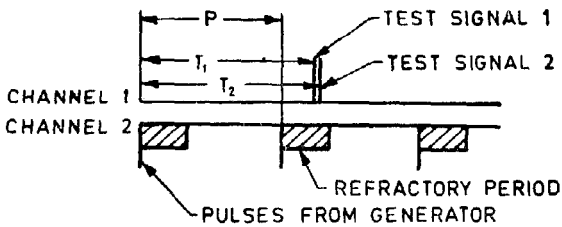


FIG. 8 INITIAL OSCILLOSCOPE DISPLAY WHEN MEASURING SENSING AND PACING REFRACTORY INTERVAL

5.7.2.3 Reduce the delay of both test signals (keeping the test signals as close as possible together) until the first test signal is sensed by the pulse generator. In case of a ventricular inhibited generator, this causes inhibition of one pulse from the generator as in Fig. 9, or the pulse generator output is triggered by the test signal as shown in Fig. 10.

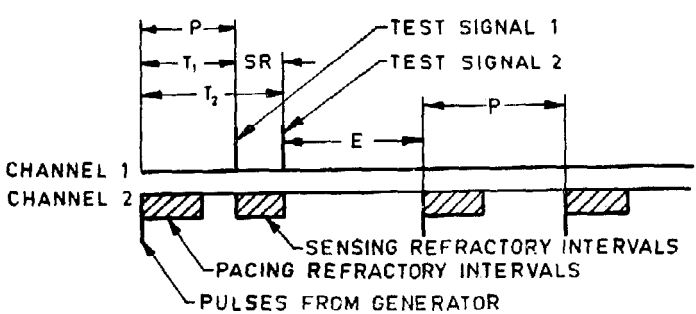


FIG. 9 MEASUREMENT OF SENSING REFRACTORY INTERVAL WITH VENTRICULAR INHIBITED PULSE GENERATOR

5.7.2.4 Increase the delay of test signal 2 until, in the case of a ventricular inhibited pulse generator, the second pulse generator pulse in Fig. 8 is delayed furher, that is, it moves to the right, as shown in Fig. 9; or in the case of a ventricular triggered pulse generator, until the third pulse generator pulse in Fig. 8 occurs sooner, at the same time as test signal 2 in Fig. 10.

5.7.2.5 The sensing refractory period is now determined by measuring the time between corresponding points on the two test signals.

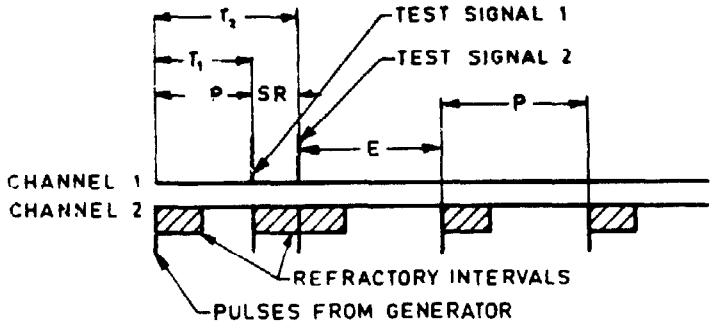


FIG. 10 MEASUREMENT OF SENSING REFRACTORY INTERVAL WITH VENTRICULAR TRIGGERED PULSE GENERATOR

5.7.2.6 Steps **5.7.2.1** to **5.7.2.5** should be repeated with test signals of amplitude approximately 2e negative.

5.8 Measurement of Packing Refractory Interval (Ventricular) Inhibited (Generators Only)

5.8.1 Circuit — Connect the pulse generator output terminals to the test load, oscilloscope and triggerable double pulse signal generator (*see* **5.2.5**) as shown in Fig. 4.

5.8.2 Method

5.8.2.1 Adjust the signal generator as in **5.6.2.2.**

5.8.2.2 Adjust the oscilloscope and signal generator as in **5.6.2.2** (*see also* Fig. 5).

5.8.2.3 Slowly increase the delay on the test signal until the third pulse generator pulse depicted in Fig. 6 is suddenly displaced to the right (*see* Fig. 11).

5.8.2.4 The interval between the second pulse generator pulse and the test pulse is the pacing refractory interval.

5.8.2.5 Steps **5.8.2.1** to **5.8.2.4** should be repeated with test signals of amplitude approximately 2e negative.

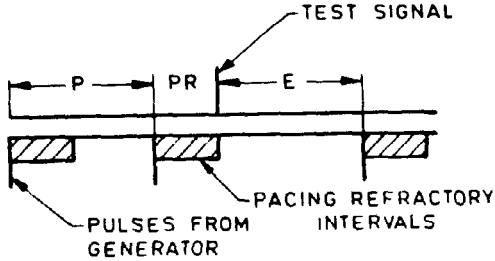


FIG. 11 MEASUREMENT OF PACING REFRACTORY INTERVAL WITH VENTRICULAR INHIBITED PULSE GENERATOR

6. LEAD TESTS

6.1 Electrical Resistance Test Conditions — The dc resistance of each conductor shall be measured under the following conditions:

a) Temperature : 27 $\pm$ 2°C

b) Test current : 10 $\pm$ 5 mA

6.2 The resistance thus measured shall be within 2 percent of declared value of the resistance.

7. NOMINAL GENERATOR SERVICE LIFE

7.1 For Non-Programmable Pulse Generators — Nominal generator service life is total time for maximum allowable decline in battery voltage at current drain on the battery for nominal parameter values with a 510 Ω load.

7.2 For Pulse Generators with Programmable Parameters — Nominal generator service life is total time for maximum allowable decline in battery voltage at current drain on the battery for nominal parameter values with a 510 Ω load with the programmed parameters set nearest the following values as applicable:

a) Pulse rate : 70 pulse/min

b) Pulse duration : 1·0 ms

c) Pulse amplitude : 4·5 V or 9·0 mA

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

Quantity	Unit	Symbol
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

Quantity	Unit	Symbol
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

Quantity	Unit	Symbol	Definition
Force	newton	N	1 N = 1 kg.m/s^2
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m^2
Frequency	hertz	Hz	1 Hz = 1 c/s (s^{-1})
Electric conductance	siemens	S	1 S = 1 A/V
Electromotive force	volt	V	1 V = 1 W/A
Pressure, stress	pascal	Pa	1 Pa = 1 N/m^2